K033641

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DEC 11 2003

SPECIAL 510(K) NOTIFICATION
COBE Cardiovascular Inc.
SMAR$_x$T VVR4000i Plus Filtered Hardshell Venous Reservoir

IX. 510(k) SUMMARY

SUBMITTER:	COBE Cardiovascular, Inc. 14401 West 65th Way Arvada, CO 80004 USA
CONTACT PERSON:	Lynne Leonard Regulatory Affairs, Submissions lynne.leonard@cobecv.com Phone: (303) 467-6214 Fax: (303) 467-6529
DATE PREPARED:	November 6, 2003
DEVICE TRADE NAME:	COBE Cardiovascular® SMAR$_x$T® VVR™ 4000i Plus Filtered Hardshell Venous Reservoir
COMMON/USUAL NAME:	Hardshell Venous Reservoir with Integral Cardiotomy Filter
CLASSIFICATION NAME:	Cardiopulmonary Bypass Blood Reservoir with Defoamer and Cardiotomy Suction Line Blood Filter
PREDICATE DEVICE:	COBE Cardiovascular® VVR™ 4000 Filtered Hardshell Venous Reservoir

DEVICE DESCRIPTION:

The COBE SMARxT VVR4000i Plus is a sealed hardshell venous reservoir with a defoamer and integral cardiotomy filter. It is a sterile device with non-pyrogenic fluid pathways, for single use only, and is not to be resterilized by the user. Certain blood contact surfaces of the oxygenator and the venous reservoir have been modified to improve blood compatibility, resulting in reduced platelet adhesion on the treated surfaces.

INDICATIONS FOR USE:

The COBE SMARxT VVR4000i Plus Sealed Hardshell Venous Reservoir is intended to be used in adult surgical procedures requiring cardiopulmonary bypass for periods up to six hours, and for postoperative chest drainage collection and autotransfusion.

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STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON:

The COBE SMARxT VVR4000i Plus Venous Reservoir described in this submission is substantially equivalent to the unmodified version, the COBE VVR4000 Venous Reservoir. The devices are identical in design, method of operation, and fundamental scientific technology. Both devices are intended to be used in adult surgical procedures requiring cardiopulmonary bypass for periods up to six hours, and for postoperative chest drainage collection and autotransfusion. The devices differ in that the COBE SMARxT VVR4000i Plus Venous Reservoir contains a surface-modifying material that improves the blood compatibility of the device.

TESTING TO DETERMINE SUBSTANTIAL EQUIVALENCE:

In-vitro tests were performed to demonstrate that the COBE Cardiovascular SMARxT VVR4000i Plus Venous Reservoir described in this submission is substantially equivalent to the unmodified version, the COBE VVR4000 Venous Reservoir.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2003

COBE Cardiovascular, Inc.
c/o Ms. Lynne Leonard
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K033641
COBE Cardiovascular® SMAR$_x$T VVR™ 4000i Plus Filtered Hardshell Venous Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Venous Reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: November 7, 2003
Received: November 20, 2003

Dear Ms. Leonard:

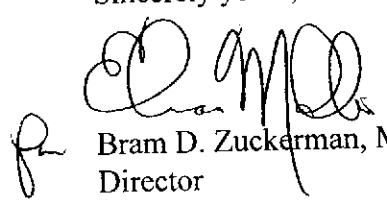
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K033641

Device Name COBE Cardiovascular® SMAR$_x$T® VVR™ 4000i Plus Filtered Hardshell Venous Reservoir

Indications for Use The COBE Cardiovascular® SMAR$_x$T® VVR™ 4000i Plus Filtered Hardshell Venous Reservoir is intended to be used in adult surgical procedures requiring cardiopulmonary bypass for periods of up to six hours, and for postoperative chest drainage collection and autotransfusion.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033641